**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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| Applicants: | Mauro et al. |
| Serial No.: | 10/003,915 |
| For: | CATAMENIAL DEVICE |
| Filed: | May 30, 2003 |
| Examiner: | Catharine L. Anderson |
| Art Unit: | 3761 |
| Confirmation No.: | 7768 |
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Attorney Docket No.: 460.2115USU

Mail Stop Appeal Brief - Patents
Commissioner for Patents
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Alexandria, VA 22313-1450

**APPEAL BRIEF FILED UNDER 35 U.S.C. §134**

Dear Sir:

Further to the Notice of Appeal and the Pre-Appeal Brief Request for Review filed on April 6, 2006, the Notice of Panel Decision from Pre-Appeal Brief Review dated June 26, 2006, and the Final Office Action dated October 6, 2005, the Appeal Brief filed herewith under 35 U.S.C. §134 and 37 C.F.R. §41.37 is believed to comply with the requirements set forth in 37 C.F.R. §41.37(c).

(1) Real Party In Interest

The real party in interest is Playtex Products, Inc. Ownership by Playtex Products, Inc. is established by the assignment document recorded for this application on November 2, 2001 on Reel 012359, Frame 0471.

(2) Related Appeals And Interferences

The undersigned attorney is not aware of any related patent applications or patents involved in any appeal or interference proceeding.

(3) Status Of The Claims

Claims 8, 9, 12, 17, 18, 24, 28 and 35 – 37 have been canceled. Claims 1 – 7, 10, 11, 13 – 16, 19 – 23, 25 – 27, 29 – 34 and 38 are pending in the present application and are the subject of this Appeal. Claims 1 and 20 are independent.

Claims 1 – 7, 10 – 11, 13 – 14, 19 – 23, 25 – 27, 29 – 32, and 38 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,559,189 to Baker, Jr. et al. ("Baker"). Claims 15 – 16 and 33 – 34 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Baker in view of U.S. Patent No. 6,335,012 to Fischetti et al. ("Fischetti").

(4) Status Of Amendments

There were no amendments made in response to the Final Office Action. The arguments on appeal are based upon the pending claims as set forth in the Claims Appendix.

(5) Summary Of Claimed Subject Matter

Independent claim 1 provides the subject matter of a tampon comprising an absorbent material and a composition disposed in the absorbent material. The composition has at least one antibacterial agent in an amount of about 0.01 wt.% to about 5 wt.% of the total weight of the tampon. See page 8, line 28 to page 9, line 4. The composition has at least one finishing agent in an amount of about 0.01 wt.% to about 10 wt.% of the total weight of the tampon. See page 11, lines 14 – 18. The composition has synergistic antibacterial properties effective to neutralize the production of TSST-1 toxin and reduce Staphylococcus aureus bacteria growth. See page 8, lines 3 – 9.

Independent claim 20 provides the subject matter of a method of inhibiting the production of TSST-1 toxin by exposing TSST-1 toxin producing Staphylococcus aureus bacteria to a tampon where the tampon has an absorbent material and a composition. The composition comprises at least one antibacterial agent in an amount of about 0.01 wt.% to about 5 wt.% of the total weight of the tampon. See page 8, line 28 to page 9, line 4. The composition has at least one finishing agent in an amount of about 0.01 wt.% to about 5 wt.% of the total weight of the tampon. See page 11, lines 14 – 18. The composition has synergistic antibacterial properties effective to neutralize the production of TSST-1 toxin and reduce Staphylococcus aureus bacteria growth. See page 8, lines 3 – 9.

(6) Grounds Of Rejection To Be Reviewed On Appeal

The first issue presented for review is whether claims 1 – 7, 10 – 11, 13 – 14, 19 – 23, 25 – 27, 29 – 32, and 38 are unpatentable under 35 U.S.C. §103(a) by U.S. Patent No. 6,559,189 to Baker, Jr. et al. ("Baker"). The second issue presented for review is whether claims 15 – 16 and 33 – 34 are unpatentable under 35 U.S.C. §103(a) over Baker in view of U.S. Patent No. 6,335,012 to Fischetti et al. ("Fischetti").

(7) Argument

**(a) Rejections under 35 U.S.C. §103**

(i) Rejection of claims 1 – 7, 10 – 11, 13 – 14, 19 – 23, 25 – 27, 29 – 32, and 38 under 35 U.S.C. §103(a) over Baker

The Final Office Action rejects claims 1 – 7, 10 – 11, 13 – 14, 19 – 23, 25 – 27, 29 – 32, and 38 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,559,189 to Baker, Jr. et al. ("Baker"). See Final Office Action p. 3.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Last, the prior art reference (or combination of references) must teach or suggest all of the claim limitations. See the *Manual for Patent Examining Practice* at §2143.03. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. See *In re Vaeck*, 947 F.2d 488, 20 USPQ 1438 (Fed. Cir. 1991).

Appellants respectfully submit that the Final Office Action has failed to establish a *prima facie* case of obviousness in its rejection of claims 1 – 7, 10 – 11, 13 – 14, 19 – 23, 25 – 27, 29 – 32, and 38, for at least the reasons set forth below. Claims 1 and 20 are argued together.

First, Baker fails to disclose or suggest all claimed features of independent claims 1 and 20, and all claims dependent therefrom. In particular, Baker does not

disclose or suggest the claimed amount of antibacterial agent, from "about 0.01 wt.% to about 5 wt.% of the total weight of the tampon"; any specific amount of finishing agent, from "about 0.01 wt.% to about 10 wt.% of the total weight of the tampon"; or any combination of the two, in a synergistic manner as recited by independent claims 1 and 20. Instead, both the Final Office Action and the Advisory Action assert that Baker's disclosure of an antibacterial agent and finishing agent in a composition are sufficient "general conditions" to render the present claims obvious because optimizing the amounts would fall within the level of one of ordinary skill in the art.

Appellants respectfully disagree, and submit that Baker's exceedingly broad disclosure of ingredients (see col. 28 to col. 32) fails to enable one of ordinary skill in the art to reach the limitations of the present claims. The specification in Baker merely lists ingredients for use in emulsions, and fails to specifically disclose any specific concentration or combinations recited by the pending claims. Without the requisite motivation for the claimed amounts, under 35 U.S.C. § 103(a), Baker cannot render the present claims obvious. To reach Appellants' claims, one of ordinary skill in the art would have to resort to undue experimentation (through trial and error of the ingredients listed in Baker) in order to discover optimum claimed concentrations of antibacterial and finishing agent, based on the total weight of the tampon.

Further, the Final Office Action mistakenly asserts that optimizing the amounts of the antibacterial agent and the finishing agent would fall within the level of one of ordinary skill in the art simply because Baker teaches the "general conditions" of the claim. However, it is not clear, and the Final Office Action has not adequately explained why one of ordinary skill in the art would have any interest or incentive whatsoever in selecting the weight percentages of antibacterial agent and finishing agent taught by the claimed invention. Clearly, there is no teaching aside from the impermissible hindsight knowledge first gained from the disclosure of the present application for modifying the weight percentages in a manner that would

have resulted in the claimed subject matter. See the *Manual for Patent Examining Practice* at §2145.

Second, Appellants respectfully submit that ranges of percentage by weight of the antibacterial agents and the finishing agents provided by the claimed invention are critical and therefore, are nonobvious. Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. See the *Manual for Patent Examining Practice* at §2144.05. The specification of the claimed invention explicitly teaches that the percentage by weight of the antibacterial agent provided is effective at significantly reducing the growth of Staphylococcus aureus bacteria that comes in contact with the tampon and the percentage by weight of the finishing agent provided is effective at significantly neutralizing toxins that come in contact with the tampon. See page 9, lines 2 – 4 and page 11, lines 16 – 18. Thus, Appellants have clearly established criticality in the ranges of percentage by weight of the antibacterial agents and the finishing agents and, therefore, the arguments made in the Final Office Action supporting a finding of obviousness are clear error.

Third, the Final Office Action mistakenly submits that since antibacterial properties are inherent in the chemicals comprising the composition of the claimed invention, Baker therefore inherently discloses a composition effective to neutralize the production of TSST-1 toxin and reduce Staphylococcus aureus bacteria growth, and thereby fulfills all limitations of the claims. The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. See *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993); see the *Manual for Patent Examining Practice* at §2112. Appellants respectfully submit that the Final Office Action fails to present any evidence, rationale or reasoning that supports a finding of inherency. Thus, it was clear error for the Final Office Action to assert that the disclosure in Baker fulfills

all features of the claimed invention based on the broad assumption that antibacterial properties are inherent in the chemicals comprising the claimed composition.

Furthermore, Baker fails to disclose or suggest all claimed features of independent claim 20 because Baker does not disclose any method of inhibiting the production of TSST-1 toxin using a composition of an antibacterial and finishing agent, based on the total weight of the tampon. Baker also fails to disclose how one of ordinary skill in the art would specifically select the antibacterial agent and finishing agent from the disclosed genus, based on total tampon weight, to reach any subsequent synergistic effect recited by Applicants' claim 20. See the *Manual for Patent Examining Practice* at §2144.08 (discussing that the prior art must provide some motivation to select the claimed species or subgenus).

Therefore, Baker fails to disclose or suggest all claimed features of claims 1-7, 10-11, 13-14, 19-23, 25-27, 29-32 and 38 and thus, *prima facie* obviousness is not established.

(ii) Rejection of claims 15 – 16 and 33 – 34 under 35 U.S.C. §103(a) over Baker in view of Fishetti

Claims 15 – 16 and 33 – 34 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Baker in view of U.S. Patent No. 6,335,012 to Fischetti et al.

As discussed above, Baker fails to render obvious independent claims 1 and 20. Claims 15 – 16 and 33 – 34 are argued together. Claims 15 – 16 and 33 – 34 are dependent upon claims 1 and 20. Appellants respectfully submit that Fischetti fails to cure the deficiencies of Baker because Fischetti also fails disclose all the features of claims 1 and 20, namely a synergistic combination of an antibacterial

agent and a finishing agent in the amount claimed, based on the total weight of the tampon.

The Final Office Action and the Advisory Action assert that Fischetti provides a basis for equivalence between the polyoxyethylene fatty acid ester and polyoxyethylene sorbital ester surfactants. More fundamentally, however, both Actions fail to point to any motivation in either Baker or Fischetti to specifically combine an antibacterial agent and a surfactant in the claimed amounts based on the total weight of the tampon. Therefore, even if one were to rely on Fischetti to demonstrate any equivalence between the surfactants, both Baker and Fischetti nonetheless fail to disclose or suggest the specific selection and amount of antibacterial agent and surfactant recited by the pending claims.

Therefore, since neither Baker nor Fischetti, taken alone or in combination, discloses or suggests all the claimed features recited in independent claims 1 and 20, Appellants submit that claims 15 – 16 and 33 – 34, which are indirectly dependent from claims 1 and 20, respectively, are patentably distinguishable over either reference. Accordingly, Appellants respectfully submit that the rejection of claims 15 – 16 and 33 – 34 under 35 U.S.C. §103(a) was clear error and cannot be sustained in view of the failure of the Final Office Action to establish a *prima facie* case of obviousness for independent claims 1 and 20 of the present application.

(iii) Summary

Accordingly, it is respectfully submitted that Baker and Fischetti, either alone or in combination, do not disclose or suggest the claims of the present application. Appellants respectfully request that the Board of Appeals reverses the final rejection of claims 1 – 7, 10 – 11, 13 – 16, 19 – 23, 25 – 27, 29 – 34, and 38, thereby enabling these claims to be allowed.

Respectfully submitted,

Dated: October 1, 2007

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(8) CLAIMS APPENDIX

Claims 1 – 7, 10, 11, 13 – 16, 19 – 23, 25 – 27, 29 – 34 and 38, herein on appeal, are set forth below.

1. (Previously presented) A tampon comprising an absorbent material and a composition disposed in said absorbent material, the composition having:

at least one antibacterial agent in an amount of about 0.01 wt.% to about 5 wt.% of the total weight of the tampon; and

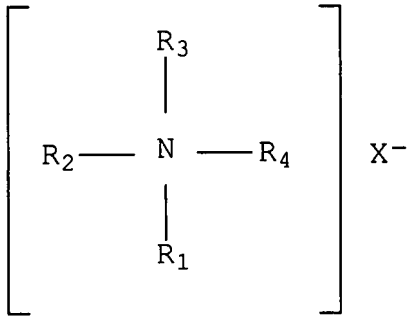
at least one finishing agent in an amount of about 0.01 wt.% to about 10 wt.% of the total weight of the tampon,

wherein the composition has synergistic antibacterial properties effective to neutralize the production of TSST-1 toxin and reduce Staphylococcus aureus bacteria growth.

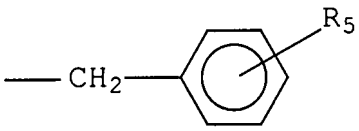
2. (Previously presented) The tampon of claim 1, wherein said at least one antibacterial agent is selected from the group consisting of: quaternary ammonium compound, glyceryl monolaurate, 5-chloro-2-(2,4-dichlorophenoxy)-2,4,4'-trichloro-2'-hydroxy diphenyl ether (triclosan), p-chloro-m-xylenol, N-(4-chlorophenyl)-N'-(3,4-dichlorophenyl) urea (triclocarban), 2-N-octyl-4-isothiazolin-3-one, iodine-based compounds, and any mixtures thereof.

3. (Previously presented) The tampon of claim 1, wherein said at least one antibacterial agent is one or more quaternary ammonium compounds.

4. (Previously presented) The tampon of claim 3, wherein said one or more quaternary ammonium compounds have a chemical structure:



wherein X is selected from the group consisting of: a halogen and a saccharinate; $R_1$ and $R_3$ is a straight or branched $C_1$-$C_4$ alkyl; $R_2$ is a straight or branched $C_6$-$C_{22}$ alkyl; and $R_4$ is of the chemical structure:



wherein $R_5$ is selected from the group consisting of: H, a straight or branched $C_1$-$C_4$ alkyl group, and a halogen.

5. (Previously presented) The tampon of claim 4, wherein said one or more quaternary ammonium compounds are selected from the group consisting of: alkyl dimethyl benzylammonium chloride, alkyl dimethyl ethylbenzylammonium chloride, myristyl dimethyl benzylammonium chloride, lauryl dimethyl ethylbenzylammonium chloride, alkyl dimethyl benzylammonium bromide, alkyl dimethyl benzylammonium cetyl phosphate, alkyl dimethyl benzylammonium saccharinate, and any mixtures thereof.

6. (Previously presented) The tampon of claim 4, wherein said one or more quaternary ammonium compounds are a mixture of alkyl dimethyl benzylammonium chloride and alkyl dimethyl ethylbenzylammonium chloride.

7. (Previously presented) The tampon of claim 6, wherein said one or more quaternary ammonium compounds are present in an amount of about 1.0 wt.% based on the total weight of the tampon.

8. (Canceled)

9. (Canceled)

10. (Previously presented) The tampon of claim 1, wherein said at least one finishing agent is one or more surfactants.

11. (Previously presented) The tampon of claim 10, wherein said one or more surfactants are selected from the group consisting of nonionic, anionic, cationic, amphoteric, and any mixtures thereof.

12. (Canceled)

13. (Previously presented) The tampon of claim 10, wherein said one or more surfactants are one or more nonionic surfactants.

14. (Previously presented) The tampon of claim 10, wherein said one or more nonionic surfactants are selected from the group consisting of one or more: alcohol ethoxylates, alkylphenol ethoxylates, carboxylic acid esters, ethoxylated anhydrosorbital esters, glycerol esters, poly(oxyethylene-co-oxypropylene) based surfactants, polyoxyethylene fatty acid amines, polyoxyethylene fatty acid esters, polyethylene glycol, polyethylene glycol esters, and any mixtures thereof.

15. (Previously presented) The tampon of claim 14, wherein said one or more nonionic surfactants are one or more polyoxyethylene fatty acid esters.

16. (Previously presented) The tampon of claim 15, wherein said polyoxyethylene fatty acid ester is present in an amount about 2.5 wt.% based on the total weight of the tampon.

17. (Canceled)

18. (Canceled)

19. (Previously presented) The tampon of claim 1, wherein said composition further comprises one or more additional components selected from the group consisting of: preservative, deodorant, fragrance, malodor counteractant material, humectant, and any combinations thereof.

20. (Previously presented) A method of inhibiting the production of TSST-1 toxin by exposing TSST-1 toxin-producing Staphylococcus aureus bacteria to a tampon, the tampon having an absorbent material and a composition, the composition comprising:

at least one antibacterial agent in an amount of about 0.01 wt.% to about 5 wt.% of the total weight of the tampon; and

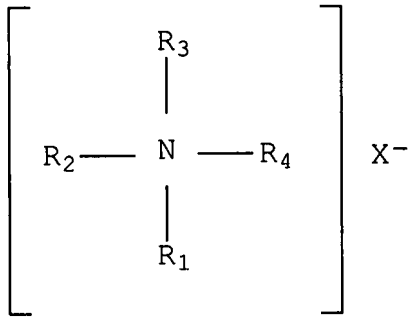
at least one finishing agent in an amount of about 0.01 wt.% to about 5 wt.% of the total weight of the tampon;

wherein the composition has synergistic antibacterial properties effective to neutralize the production of TSST-1 toxin and reduce Staphylococcus aureus bacteria growth.

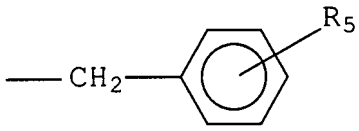
21. (Original) The method of claim 20, wherein said at least one antibacterial agent is selected from the group consisting of: quaternary ammonium compound, glyceryl monolaurate, 5-chloro-2-(2,4-dichlorophenoxy)-2,4,4'-trichloro-2'-hydroxy diphenyl ether (triclosan), p-chloro-m-xylenol, N-(4-chlorophenyl)-N'-(3,4 dichlorophenyl) urea (triclocarban), 2-N-octyl-4-isothiazolin-3-one, iodine-based compounds, and any mixtures thereof.

22. (Previously presented) The method of claim 20, wherein said at least one antibacterial agent is one or more quaternary ammonium compounds.

23. (Original) The method of claim 22, wherein said one or more quaternary ammonium compounds has a chemical structure:



wherein X is selected from the group consisting of: a halogen and a saccharinate; $R_1$ and $R_3$ is a straight or branched $C_1$-$C_4$ alkyl; $R_2$ is a straight or branched $C_6$-$C_{22}$ alkyl; and $R_4$ is of the chemical structure:



wherein $R_5$ is selected from the group consisting of: H, a straight or branched $C_1$-$C_4$ alkyl group, and a halogen.

24. (Canceled)

25. (Previously presented) The method of claim 21, wherein said one or more quaternary ammonium compounds are selected from the group consisting of: alkyl dimethyl benzylammonium chloride, alkyl dimethyl ethylbenzylammonium chloride, myristyl dimethyl benzylammonium chloride, lauryl dimethyl ethylbenzylammonium chloride, alkyl dimethyl benzylammonium bromide, alkyl dimethyl benzylammonium cetyl phosphate, alkyl dimethyl benzylammonium saccharinate, and any mixtures thereof.

26. (Original) The method of claim 25, wherein said one or more quaternary ammonium compounds are a mixture of alkyl dimethyl benzylammonium chloride and alkyl dimethyl ethylbenzylammonium chloride.

27. (Previously presented) The method of claim 25, wherein said one or more quaternary ammonium compounds are present in an amount about 1.0 wt.% based on the total weight of the tampon.

28. (Canceled)

29. (Original) The method of claim 20, wherein said at least one finishing agent is one or more surfactants.

30. (Original) The method of claim 29, wherein said one or more surfactants are selected from the group consisting of: nonionic, anionic, cationic, amphoteric, and any mixtures thereof.

31. (Original) The method of claim 29, wherein said one or more surfactants are one or more nonionic surfactants.

32. (Original) The method of claim 31, wherein said one or more nonionic surfactants are selected from the group consisting of: alcohol ethoxylates, alkylphenol ethoxylates, carboxylic acid esters, ethoxylated anhydrosorbital esters, glycerol esters, poly (oxyethylene-co-oxypropylene) based surfactants, polyoxyethylene fatty acid amines, polyoxyethylene fatty acid esters, polyethylene glycol, polyethylene glycol esters, and any mixtures thereof.

33. (Original) The method of claim 32, wherein said one or more nonionic surfactants are one or more polyoxyethylene fatty acid esters.

34. (Previously presented) The method of claim 33, wherein said one or more polyoxyethylene fatty acid esters are present in an amount about 2.5 wt.% based on the total weight of the tampon.

35. (Canceled)

36. (Canceled)

37. (Canceled).

38. (Original) The method of claim 20, wherein said composition further comprises one or more additional components selected from the group consisting of: preservative, deodorant, fragrance, malodor counteractant material, humectant and any combinations thereof.

(9) EVIDENCE APPENDIX

There is no entered evidence submitted herewith.

(10) RELATED PROCEEDINGS APPENDIX

As discussed above, there are no other appeals or interferences known to appellants, appellants' attorney or the owner assignee of the application (Playtex Products, Inc.), which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal. Thus, no copies of decisions rendered by a court or the Board are included herewith.